

EXHIBIT A

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OF COUNSEL:
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* ALSO ADMITTED IN GA
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June 28, 2013

VIA HAND DELIVERY

C.J. Gideon
Gideon Cooper & Essary
315 Deaderick St., Suite 1100
Nashville, Tennessee 37238

**Re: New England Compounding Center Litigation, MDL No. 2419
Subpoena to Howell Allen Clinic**

Dear C.J.:

We are in receipt of your letter from June 25, 2013 related to a subpoena (the "Howell Allen Subpoena") we served in the above-identified MDL action (the "MDL Action") on your client, Howell Allen Clinic ("Howell Allen"). This letter is in response to that letter and an attempt by the Plaintiffs' Steering Committee ("PSC") to meet and confer with you regarding the Howell Allen Subpoena.

Before addressing each objection you raised in your letter, I wanted to address some preliminary matters. First, since issuance of the Howell Allen Subpoena, Judge Saylor has issued both the HIPPA Qualified Protective Order (Dkt. No. 192, the "Qualified Protective Order") and the Order on Central Enforcement (Dkt. No. 193) referenced in the cover letter to the Howell Allen Subpoena. These orders are attached for your convenience to this letter. According to the Order on Central Enforcement, Judge Saylor will hear any objections to the Howell Allen Subpoena at the July 18, 2013 hearing, and to the extent that we are unable to resolve issues in this meet and confer process before then, we would expect you to make any objections at that hearing so that Judge Saylor can rule on the validity of any outstanding objection.

Next, to the extent that the July 8, 2013 date does not work for the noticed deposition, we are obviously willing to accommodate any reasonable request on rescheduling. We suggest you provide dates between July 8, 2013 and July 22, 2013 that may be convenient for you to hold this deposition. Scheduling of this deposition will also require the PSC coordinate with other defense counsel, so the sooner you provide dates, the sooner we can coordinate with all interested parties. We will consider a reasonable extension of the deposition beyond July 22, 2013 so long as responsive documents are produced to the PSC in a reasonable timeframe.

To the extent that you may require additional time to produce responsive documents, we would consider a reasonable extension on this requirement, so long as you agree to produce responsive documents no later than July 22, 2013.

An alternative option is also for your client to enter into the mediation process being developed by the Court, along with the PSC and the Creditor's Committee. To the extent that Howell Allen is willing to opt into this mediation process, we are willing to postpone all deadlines in the Howell Allen Subpoena and pursue resolution of any claims against Howell Allen through the mediation process.

Finally, you claim that the Howell Allen Subpoena failed to attach Exhibit B. We find this to be implausible as our records reveal that the envelope given to our process server contained the attached Exhibit B. The error appears to have occurred on your end. In any event, and out of an abundance of caution, we include the Howell Allen Subpoena in full with this letter.

I. The Howell Allen Subpoena Does Not Exceed The Scope of Discovery Approved By The Court

You incorrectly claim that the Howell Allen Subpoena exceeds the scope of discovery permitted by the Court. Judge Saylor in his decision lifting the stay of discovery did not in any way impose any limitations upon the PSC's ability to obtain discovery from clinics.

In any event, your claims that Howell Allen did not purchase NECP products rings hollow in light of its relationship with St. Thomas Outpatient Neurosurgical Center ("STOPNC"). STOPNC was one of the largest, if not the largest, purchaser of NECP products in the country. Howell Allen is part owner of STOPNC, the individuals working at STOPNC are Howell Allen employees, Howell Allen doctors staff STOPNC, and Howell Allen's front page on its website contains a ribbon in red across the top of its screen stating "Epidural Steroid Injections at St. Thomas Outpatient Neurosurgical Center" which contains a link to St. Thomas' website related to the fungal meningitis outbreak.

Given these facts, which you know, an overly technical reading on purported limitations of discovery is wholly misplaced, and we believe Judge Saylor will not appreciate these types of games in discovery. Accordingly, any attempt by you to refuse to comply with the Howell Allen Subpoena on this basis is misplaced and improper.

II. The PSC Has Authority To Obtain Discovery Of Information Regarding Patients That Are Not Currently Plaintiffs In The MDL

Your claim that the PSC is not entitled to discover information related to patients that are not currently plaintiffs in the MDL Action is incorrect for several reasons. First, subsumed in the MDL Action are numerous class actions which relate to all potential plaintiffs that were exposed to tainted products produced by the New England Compounding Pharmacy ("NECP"). See e.g., *McDow et al. v. New England Compounding Pharmacy, Inc. et al.*, 1:12-cv-12112-FDS (D.

Mass.) To the extent that the Howell Allen Subpoena seeks information related to the identity of putative class members, that information is clearly discoverable by the PSC in the MDL Action. *Davis v. Chase Bank U.S.A., N.A.*, Case No. 06-04804, 2010 U.S. Dist. LEXIS 37464, * 7-8 (C.D. Cal. April 14, 2010) (“Contact information regarding the identity of potential class members is generally discoverable, so that the lead plaintiff may learn the names of other persons who might assist in prosecuting the case.”) Since, the PSC is charged with engaging in discovery for “all plaintiffs” including these class plaintiffs, your claims that the discovery is limited strictly to those plaintiffs that the PSC represents is wholly misplaced.

Even if the class claims were not pending in the MDL Action, the information requested by the Howell Allen Subpoena would still be discoverable by the PSC. The MDL Action obviously includes hundreds of individual plaintiffs and the PSC is charged with conducting discovery for all of these individuals. Information related to other patients that also received similar injections at similar times from the same NECP lot number is highly probative evidence related to establishing a causal connection between the harms suffered by named plaintiffs and the actions of NECP in providing and treating physicians in using tainted NECP products. The information sought in the Howell Allen Subpoena will allow the PSC to investigate these similarities and contact potential witnesses. Given the broad reach of discovery under Rule 26, there is simply no basis to claim that this information is not relevant to the hundreds of individual plaintiff claims asserted in the MDL Action. *See e.g., General Electric Co. v. NLRB*, 916 F.2d 1163, 1168 (7th Cir. 1990) (relevance is most often viewed liberally to allow for broad disclosure of information).

Moreover, in his Qualified Protective Order, Judge Saylor granted the PSC broad authority to subpoena clinic records that contained HIPAA-protected information of all individuals, not simply those the PSC represents. It is simply inconceivable that Judge Saylor would grant this broad authority and then sustain your objection that the PSC lacked the authority to obtain this information.

You are also incorrect in that only the Creditor’s Committee can request this information. The PSC issued the Howell Allen Subpoena, with Judge Saylor’s approval, in conjunction with the Creditors’ Committee and it is anticipated that both the Creditor’s Committee and the PSC will have access to the HIPAA-protected personal health information once that information is produced in accordance with the Qualified Protective Order.

Further, you are incorrect in your claim that the Howell Allen Subpoena violates the Qualified Protective Order in that it requires production of HIPAA-protected personal health information (“PHI”) at the noticed deposition. The cover letter accompanying the Howell Allen Subpoena clearly states that any PHI should only be produced to the PSC-designated vendor and should not be brought to the deposition. The PSC is continuing its work on obtaining the vendor required by the Court’s Qualified Protective Order and will notify you once that vendor has been selected. In the meantime you should continue to gather the information requested by the Howell Allen Subpoena so that it can be timely produced to this vendor.

To the extent that your refusal to produce documents pursuant to the Howell Allen Subpoena is based on a failure of the Qualified Protective Order to accompany the subpoena, this

refusal is misplaced. As mentioned above, that order had not been issued at the time the PSC issued the Howell Allen Subpoena. The PSC could hardly serve the subpoena along with a document that did not exist when it served the Howell Allen Subpoena. As mentioned above, that order is attached to this letter, and accordingly there are simply no grounds to refuse to produce documents or otherwise comply with the Howell Allen Subpoena for the PSC's inability to serve the Howell Allen Subpoena along with a copy of the Qualified Protective Order.

Finally, your claim that "there is no exception to HIPAA permitting or authorizing Howell Allen to disclose the name of patients who received medication manufactured and sold by NECP to the PSC" rings hollow in light of the plain language of the statute and Judge Saylor's Qualified Protective Order. HIPAA permits disclosure of PHI when requested by a subpoena accompanied by a qualified protective order. 45 C.F.R. § 164.512(e)(1)(ii)(B). That is the case here, the Howell Allen Subpoena requires production of PHI and a qualified protective order is in place.

Accordingly, we request that you continue to gather HIPAA-protected information requested by the Howell Allen Subpoena and be prepared to produce this material on July 21, 2013 (or thirty days after the PSC served the Howell Allen Subpoena) or on the date on which we identify the vendor required by Judge Saylor's Qualified Protective Order, whichever is later.

III. The Subpoena Is Not Overly Broad and Not Unduly Burdensome

Next you allege that the subpoena violates the PSC's duty under Rule 45(c)(1) in that the PSC failed to take reasonable steps to avoid imposing undue burden or expense on your client. As an initial matter, the PSC agrees to limit the scope of the Howell Allen Subpoena to require production of HIPAA-protected information only from January 2011-November 2012. This restricted time frame is applicable solely to information covered by the Court's Qualified Protective Order and does not otherwise limit the scope of any other request contained in the Howell Allen Subpoena.

You next claim, without any support, that your client could not produce this information in the time required without "impairing the normal course of business." We find this to be unlikely. Your client, like every medical provider, must get routine requests for the production of medical records similar to those contained in the Howell Allen Subpoena and we find it simply impossible to believe that your client could not process this request in a reasonable time with minimum interruption to its business operations. Accordingly, we request that you comply with the Howell Allen Subpoena and produce documents as required therein.

Next, you claim, again without any citation to authority, that Howell Allen is relieved of its obligation to respond to the Howell Allen Subpoena because it previously produced documents in a state court action that was not part of the MDL Action. This is inappropriate. Simply because Howell Allen produced documents in one litigation does not relieve it of any responsibility to fully respond to the Howell Allen Subpoena. In fact, this argument cuts heavily against your claim that the Howell Allen Subpoena imposes an undue burden because apparently Howell Allen has responsive documents in a ready format for production. Presumably there is some overlap between these previously produced documents and the documents requested by the

Howell Allen Subpoena. Accordingly, we would request that you produce all documents previously produced in the state court litigation and responsive to the Howell Allen Subpoena by the date specified in the Howell Allen Subpoena. This of course would not relieve you of fully responding to the Howell Allen Subpoena to the extent that it requires a broader production than the one you produced in the state court litigation.

Finally, to the extent that you may wish to avoid a deposition because of the PSC's failure to tender the required witness fees, we tender the required \$40 witness fee with this letter. We believe this satisfies the requirement of providing witness fees and do not believe that this is a valid basis for not otherwise satisfying your obligations to respond and prepare for a deposition pursuant to the Howell Allen Subpoena. To the extent that you require re-service of the Howell Allen Subpoena please let us know immediately.

IV. The Subpoena's Time Of Compliance Is Reasonable

You next claim, without any citation to any support whatsoever, that the subpoena does not allow a reasonable time because it only permits 21 days for compliance. Presumably your failure to cite to any authority for your proposition that a 21-day compliance period is "unreasonable" is due to the mountain of case law that holds that a shorter period, 14 days to be exact, is presumptively reasonable time for compliance. *See e.g., In re Rule 45 Subpoena to Fidelity Nat'l Info. Servs., Inc.*, No. 3:09-mc-29-J-25TEM, 2009 U.S. Dist. LEXIS 122142, (M.D. Fla. Dec. 11, 2009) (holding that 14 days to respond to a subpoena is presumptively reasonable under Rule 45) (citing *McClendon v. TelOhio Credit Union, Inc.*, No. 2:05-CV-1160, 2006 U.S. Dist. LEXIS 57222, 2006 WL 2380601 (S.D. Oh. Aug. 14, 2006)); *Biological Processors of Alabama, Inc. v. North Georgia Environmental Services, Inc.*, Mis. Action No. 09-3673, 2009 U.S. Dist. LEXIS 60371, *3 (E.D. La. July 15, 2009) (citing additional cases); *Tutor-Saliba Corp. v. U.S.*, 30 Fed. Cl. 155, 156-57 (Fed. Cl. 1993); *see also Mann v. University of Cincinnati*, 114 F.3d 1188 (Table), 1997 WL 280188, at *5 n. 5 (6th Cir. 1997).

Further, you are incorrect that the Howell Allen subpoena requires production of PHI in violation of the Court's Qualified Protective Order. As is made clear by the cover letter that accompanied the Howell Allen Subpoena, responsive documents that require the production of HIPAA-protected information should be produced in accordance with the Court's Qualified Protective Order. Accordingly, we would expect that that information would be produced within the time period prescribed by the Order, not sooner.

Finally, there is no rule and you cite to no authority for the absurd proposition that "the deposition cannot occur before we have had an opportunity to quash and/or object to the subpoena." The only limitation in the Federal Rules on the time for requiring production is that contained in Rule 45(c)(3), which **only** requires a "reasonable time" to allow for a party to comply with a subpoena (the Rule says nothing about giving a party appropriate time to have a motion to quash heard and we have been unable to find any case-law supporting such an absurd proposition). As already explained above, the 21 days response time is well within the range of reasonableness regularly accepted by federal courts.

Notwithstanding the above, to the extent that you need a reasonable extension on the time to provide responsive documents, as explained above, the PSC will consider a reasonable extension in a good faith effort to meet and confer with your client on the requirements of the Howell Allen Subpoena. However, the PSC will not permit an extension beyond July 22, 2013 unless Howell Allen opts into the mediation process.

V. The Subpoena Does Not Exceed The Scope of FRCP 26

You next claim that because no claim or defense related to Howell Allen is pending in the MDL Action, "the vast majority of the information sought exceeds the permissible scope of discovery." Judge Saylor obviously disagrees as he did not limit discovery to only those clinics that have pending matters in the MDL Action. Indeed, if discovery were so limited, subpoenas would not be required to be issued as a simple request for production or notice of deposition would have sufficed to obtain the discovery requested. Instead, Judge Saylor explicitly permitted the PSC to issue subpoenas to clinics involved in providing NECP products to patients. You do not claim that Howell Allen did not provide patients with NECP products, nor could you, as Howell Allen is one of the many clinics explicitly identified by the Center for Disease Control that received tainted MPA from NECP.


Moreover, under the twisted logic used in your letter, no subpoena could ever seek relevant information under Rule 26 because subpoenas are by definition issued to non-parties. Howell Allen's status as a non-party does not limit or detract from the fact that Howell Allen has information relevant to claims made in the MDL Action in its possession, custody, and/or control and that the PSC can request this information via a Rule 45 subpoena.

Therefore, your attempts to limit the scope of the Howell Allen Subpoena are misplaced and we request that you not withhold any documents or other discovery based on this unsupported and unfounded basis.

VI. The Subpoena Does Not Request Privileged Information

Finally, you claim that the Howell Allen Subpoena seeks discovery over information protected by the Tennessee Patient Safety and Quality Improvement Act. However, you fail to provide sufficient information for the PSC to evaluate your privilege claim. We suggest that, once you produce documents, any document withheld on the basis of this, or any other applicable privilege, be documented in an appropriate privilege log so that the PSC may evaluate your claims of privilege. Once a privileged log has been provided, we can discuss whether any claims of privilege should be put before Judge Saylor.

Sincerely,

 w/ permission by 
J. GERARD STRANCH, IV
Member of PSC and Tennessee Chair

Enclosure:

cc: Tom Sobol
All Other PSC Members

BRANSTETTER, STRANCH & JENNINGS, PLLC

29033

HOWAL	Howell Allen Clinic	06/28/13	29033	\$40.00
<u>Invoice #</u>	<u>Date</u>	<u>Our Ref #</u>	<u>Reference</u>	<u>Invoice Amt</u>
06282013	06/28/13	33684	Client Charge: 12-496; subpoena witness fee; BG/bm	\$40.00

ORIGINAL DOCUMENT PRINTED ON CHEMICAL REACTIVE PAPER WITH MICROPRINTED BORDER

**BRANSTETTER, STRANCH
& JENNINGS, PLLC**

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NATIONAL BANK

87-863/640

29033

NUMBER

29033

HOWAL

Forty and NO/100 Dollars

DATE

06/28/13

AMOUNT

\$40.00

BRANSTETTER, STRANCH & JENNINGS, PLLC

Howell Allen Clinic
ORDER OF 2011 Murphy Ave # 401

Nashville, TN 37203

Ronald L. Schuler

THIS DOCUMENT CONTAINS HEAT SENSITIVE INK. TOUCH OR PRESS HERE - RED IMAGE DISAPPEARS WITH HEAT

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BRANSTETTER, STRANCH & JENNINGS, PLLC

29033

HOWAL	Howell Allen Clinic	06/28/13	29033	\$40.00
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06282013	06/28/13	33684	Client Charge: 12-496; subpoena witness fee; BG/bm	\$40.00

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt.: 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

All Actions

**ORDER ON
CENTRAL ENFORCEMENT OF SUBPOENAS**

WHEREAS the Plaintiffs' Steering Committee has advised the Court that it intends to issue subpoenas to:

- Pain clinics, hospitals, and other entities or individuals who purchased NECC's methyl prednisolone acetate, cardioplegic solution, or ophthalmic solution;
- Vendors and contractors who worked on or were responsible for the conditions of the NECC facility;
- Vendors who conducted sterility or other testing of NECC's products or equipment used to make the products; and
- Suppliers who provided the raw materials used to create methyl prednisolone acetate, cardioplegic solution, or ophthalmic solution.

WHEREAS the Court has the authority to enforce subpoenas issued out of the MDL;

WHEREAS the Court finds that central enforcement of these subpoenas will promote efficiency and the interests of justice;

IT IS HEREBY ORDERED

1. This Court will centrally enforce subpoenas issued out of the MDL.
2. Any objections or motions to quash subpoenas issued out of the MDL shall be filed directly into the MDL. Attorneys are permitted to make a limited appearance for the purposes of contesting a subpoena without being deemed to otherwise consent to the jurisdiction of this Court.

3. Objections to subpoenas served before July 10, 2013 will be heard during the July 18, 2013 status conference.

SO ORDERED.

Dated this 21st day of June, 2013.

/s/ F. Dennis Saylor

F. Dennis Saylor, IV
United States District Judge

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt.: 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

All Actions

**ORDER GRANTING PLAINTIFFS LEAVE
TO SERVE SUBPOENAS AND QUALIFIED PROTECTIVE
ORDER REGARDING PROTECTION OF HEALTH INFORMATION**

WHEREAS, the Court recognizes that protected health information may be produced in response to subpoenas issued by parties in the MDL;

WHEREAS, nothing in this order shall deprive a subpoena recipient of the opportunity to object to requests to produce such protected information;

WHEREAS, the Court desires to establish an up-front process for the production of any such protected health information in compliance with applicable federal and state law.

IT IS HEREBY ORDERED that “Personal Health Information,” and “individually identifiable health information” protected under the Health Insurance Portability and Accountability Act of 1996 (hereinafter “HIPAA”) (42 USC §1320d et seq.) and the regulations promulgated thereunder (45 CFR §§160, 164 et seq.), shall only be disclosed as follows:

1. Healthcare facilities and/or providers that have examined, tested or treated patients who have been identified as recipients of one or more of New England Compounding Pharmacy, Inc. (“NECC”) solutions, medications or compounds, shall produce protected health information pursuant to this order and a subpoena issued by Plaintiffs.

2. The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January, 2011 – November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

3. All protected health information produced pursuant to this order shall be produced in electronic or hard copy format only to a third party vendor (the "Vendor") to be selected jointly by the Plaintiffs' Steering Committee, the chapter 11 trustee appointed in NECC's chapter 11 case (the "Trustee"), and the Official Committee of Unsecured Creditors appointed in NECC's chapter 11 case (the "Official Committee"), after meeting and conferring.

4. The Vendor shall hold such protected health information in the strictest confidence and shall not release such information to any other person or entity until further order of this Court.

5. In the case of electronic data, the Vendor shall maintain the obtained protected health information on a server that is housed in a data center secured and hardened against unauthorized access or download, including unauthorized access via the Internet or any wireless device. The information obtained in electronic form pursuant to the subpoenas shall be loaded to a database that is password-protected and encrypted. The Vendor shall maintain similar protections against unauthorized access to any protected information produced in hard copy format.

6. The documents, data, or other information produced pursuant to the subpoenas and this Order shall be provided for the sole purposes of (i) investigating, litigating and resolving potential claims involved in this litigation; (ii) litigating and resolving potential claims in the chapter 11 case of NECC (the "Chapter 11 Case"); and (iii) the administration of the Chapter 11 Case, and not for any other purpose. In the event Defendants wish to use documents, data or other information produced pursuant to the subpoenas and this Order, they may seek permission of the Court to do so.

7. Within thirty (30) days of entry of this Order, the Plaintiffs' Steering Committee, Defense Liaison counsel, the Trustee, and the Official Committee shall propose to the Court a protocol for sharing the protected health information housed by the Vendor with necessary parties approved by the Court, including without limitation, their experts for purposes of providing expert reports and or analysis. That proposed protocol will also seek to ensure that any such protected health information shared with other parties or experts is provided a level of security against unauthorized disclosure that is compliant with HIPPA.

8. Nothing in this Order authorizes direct communications between defendants, their counsel or other agents or representatives and the patients' healthcare providers providing disclosure pursuant to this Order, nor does it bar such communications.

9. The Vendor shall maintain the information received in connection with the subpoenas until the later of (i) one (1) year after the resolution of this matter or (ii) one (1) year after the resolution of all claims in NECC's chapter 11 case (in either case, the "Retention Period"), or as otherwise ordered by the Court. At the end of the Retention Period, or as ordered by the Court, it shall destroy any and all originals and copies of the information obtained, including electronic and hard copies.

10. Plaintiffs' Counsel are authorized to serve subpoenas issued by this Court on the entities listed in NECC's Customer list located at:
<http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf> as well as Pharmacy Support, Inc., CuraScript, Inc., and Clint Pharmaceuticals.

11. All subpoenaed entities that provide requested information shall be deemed to fall within the safe harbor of HIPAA for court-ordered production of personal health information, 45 C.F.R. § 164.512(e)(1), and shall have no liability under HIPAA or any other federal or state statute, regulation, or other requirement related to protected health information, for supplying patient or member information to the Vendor.

12. The Vendor shall not be deemed to be a guarantor of the completeness and accuracy of the data provided to it and shall have the right to rely in good faith upon the information provided by any subpoenaed entity.

13. The subpoenaed entities are to use their best effort to supply the requested information.

14. The subpoenaed entities must produce the requested information to the Vendor within 30 days of receipt of the subpoena.

15. A copy of this Order shall be appended to the subpoenas.

SO ORDERED.

Dated this 21st day of June, 2013.

/s/ F. Dennis Saylor
F. Dennis Saylor, IV
United States District Judge